

REMARKS

I. Status of the Application

Claims 46-55, 61-87 and 89 are presently pending in the instant application. Claims 77-84, 87 and 89 have been cancelled without prejudice to the filing of any appropriate continuation applications as being directed to non-elected subject matter. New claims 90-93 have been added. Claims 48, 63-66 and 75 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 46-55, 61-76, 85 and 86 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 46-55, 62-71, 73-76, 85 and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. Claim 72 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al., and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619.

Applicants have amended the claims under consideration to more clearly define and distinctly characterize Applicants' novel invention. Specifically, Applicants have amended claim 46 to remove certain claim language. Claim 50 was amended to correct a typographical error. Claim 52 was amended to address formal matters. Support for new claim 90 can be found in the published application at least at paragraph [0042], where Applicants teach minerals present at a concentration of between 1.5 to 15 g/l; at paragraph [0036], where Applicants teach inositol, ribose, galactose and mannose; and at paragraph [0047], where Applicants teach a nitrogen concentration of not more than 3 g/l. Support for new claim 91 can be found in the published application at least at paragraph [0029], where Applicants teach treatment of dehydration in ill subjects. Support for new claim 92 can be found in the published application at least at paragraph [0029] where Applicants teach

treatment of hospital patients who stay in bed, and patients in a coma, and at paragraph [0006], where Applicants teach chronic hypohydration caused by drugs having a diuretic action, spinal cord injuries and kidney dysfunction.

The amendments contain no new matter. Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance.

II. Claims 48, 63-66 and 75 Are Definite

At page 4, section 3 of the instant Office Action, claims 48, 63-66 and 75 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The second paragraph of 35 U.S.C. § 112 states that:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

It is well settled that a claim must “reasonably apprise those skilled in the art both of the utilization and scope of the invention.” *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 134-38, 118 U.S.P.Q. 122, 130 (2d Cir. 1958), *cert. denied*, 358 U.S. 884 (1958). Claims 48, 63-66 and 75 meet this standard.

With respect to claims 48 and 75, the Office Action asserts that it is not clear what the lower limit of the claimed dry mass content or nitrogen content are in the claimed composition. The MPEP states, “Applicants...are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained.” MPEP

2173.05(a). Applicants submit that claims 48 and 75 are definite because one of skill in the art would clearly and precisely understand that which is claimed, specifically, a dry mass content of less than 9% or a nitrogen content of less than 3 g/l. The Office Action asserts that, since the interpretation of the claimed range allows for the inclusion of zero, the claims leave the reader in doubt as to the meaning of the invention. Applicants respectfully submit that the claims require a certain amount of dry mass, and to interpret a dry mass content of less than 9% as including 0 would render Applicants' claimed invention meaningless. It would be obvious to one of skill in the art, within the facts of the instant application, that the claims must have at least a very small amount of dry mass, such that the range would be from less than 9% to this small amount. One of skill in the art would also understand that the claimed invention would contain at least a small nitrogen content. Accordingly, Applicants respectfully request that the rejection of claims 48 and 75 be reconsidered and withdrawn.

With respect to claims 63-66, the Office Action states that it is not clear what the claimed mineral concentration is. Claims 63-66 are directed in part to fluids having the claimed mineral at a claimed concentration of 100 mg/l (magnesium, claim 63), 10 mg/l (zinc, claim 64), 300 mg/l (calcium, claim 65) or 5 mg/l (iron, claim 66) or more. The Office Action asserts that, since the specification does not define the upper limit of the claimed range of magnesium, zinc, calcium and iron, the claims render for the reader doubt as to the meaning of the invention to which they refer. Applicants disagree. The pending claims require a solution having a hypotonic osmolarity in the range of 70 to 275 mOsm/l. Osmolarity is defined as the number of dissolved components per liter, and 1 Osm/l means 1 mole of dissolved components per liter (paragraph [0020] of the published application)].

The pending claims further require the presence of 0.2 – 10 g/l methyl amine and 20-75 g/l digestible carbohydrate. Based on composition of the fluid (i.e., the amount of methyl amine and digestible carbohydrate present, as well as any other components), in order to make the claimed fluid having the claimed osmolarity, one of skill in the art would understand that only certain concentrations of minerals could be included while maintaining an osmolarity of between 70 and 275 mOsm/l. Accordingly, one of skill in the art would recognize the upper limit of the claimed range. Thus, Applicants respectfully request that the rejection of claims 63-66 be reconsidered and withdrawn.

III. Claims 46-55, 61-76, 85 and 86 Are Enabled

At page 3, section 2 of the instant Office Action, claims 46-55, 61-76, 85 and 86 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the specification, while being *enabling* for a fluid for *treating hypohydration*, does not reasonably provide enablement for a fluid for “preventing.”

Without acquiescing to the rejection, Applicants respectfully submit that claim 46 was amended to remove the language “preventing.” Accordingly, claim 46 and claims depending therefrom are now directed in part to a fluid for treating hypohydration. Thus, Applicants respectfully request that the rejection of claims 46-55, 61-76, 85 and 86 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement be reconsidered and withdrawn.

IV. Claims 46-55, 62-71, 73-76, 85 and 86 Are Nonobvious over Simone, Thomas et al., Buchholz et al. and Hageman et al.

At page 6, section 4 of the instant Office Action, claims 46-55, 62-71, 73-76, 85 and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. The Office Action states that, although the instant claims use different names for the claimed ingredients than those taught in the cited references, the references are pertinent and relevant because all the claimed species and their roles are well taught in the cited references. The Office Action concludes that one would have been motivated to combine the references and make the modifications because they are drawn to the same technical fields, and pertinent to the problem that Applicants are concerned about.

Applicants respectfully traverse this rejection. Applicants respectfully submit that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. The cited references fail to teach or suggest Applicants' claimed invention.

Claim 46 and claims depending therefrom are directed in part to a fluid for *treating hypohydration*, comprising at least one methyl amine, one or more digestible carbohydrates and one or more minerals, wherein the methyl amine is selected from *dimethylglycine* and *sarcosine* and the fluid has an essentially *hypotonic osmolarity* in the range of *70 to 275 mOsm/l*.

Hypohydration can cause mechanical and chemical damage to tissue, resulting in fatigue, pain, and even dysfunction of organs such as the liver, heart, pancreas and kidneys (paragraph [0004] of the published application). Applicants teach that their novel, hypotonic fluid contributes to the prevention of water disturbances, to homeostasis and to a rapid restoration of bodily water content

after dehydration (paragraph [0018], published application). The claimed hypotonic fluid further protects against secondary effects of hypohydration, while minimizing undesired side effects (paragraph [0018], published application). Applicants' claimed fluids are an advance over hypertonic fluid compositions known in the art that, because of their hypertonic nature, are not as effective as the claimed composition in alleviating hypohydration, and can cause possible side effects in a hypohydrated user, such as altering the levels of endogenous compounds such as minerals, amines and glucose as well as contributing to tissue and organ dysfunction (paragraphs [0008] - [0018] of the published application).

Simone fails to teach or suggest each and every limitation of the claimed invention. The Office Action asserts that Simone teaches a hypotonic rehydration or nutritional drink. Applicants respectfully disagree. Nowhere does Simone teach or suggest a hypotonic fluid for preventing hypohydration, or that a hypotonic drink would provide any benefits in treating hypohydration. Further, Simone fails to teach or suggest a specific osmolarity, let alone Applicants' claimed osmolarity of between 70 and 275 mOsm/l. Finally, Simone fails to teach a composition including sarcosine or dimethylglycine. The secondary references fail to cure the deficiencies of Simone.

Thomas et al. is directed to nutraceutical compositions having cytoprotective agents (column 3, lines 59-61). Thomas et al. is completely silent with respect to a hypotonic fluid for treating hypohydration, let alone a hypotonic solution having Applicants' claimed osmolarity of between 70 and 275 mOsm/l. Thomas et al. also fails to teach a composition including sarcosine or dimethylglycine.

Buchholz et al. is directed to compositions for the treatment and prevention of transmethylation disorders such as neurological and pathophysiological diseases (column 1, lines 4-9), not for the treatment of hypohydration. Nowhere does Buchholz et al. teach or suggest a

hypotonic fluid, let alone a hypotonic fluid having a specific osmolarity such as between 70 and 275 mOsm/l, as claimed by Applicants.

Hageman et al. is directed to nutritional preparations including ribose and folic acid to support total nucleotide metabolism (column 5, lines 8-12). Hageman et al. does not teach or suggest fluids for treating hypohydration, hypotonic fluids, or an osmolarity of 70 to 275 mOsm/l, as claimed by Applicants. Hageman et al. also fails to teach a composition including sarcosine or dimethylglycine.

Thus, the cited references, alone or in combination, fail to teach or suggest each and every element of Applicants' claimed composition. Accordingly, Applicants respectfully request that the rejection of claims 46-55, 62-71, 73-76, 85 and 86 under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342 be reconsidered and withdrawn.

V. Claim 72 Is Nonobvious over Simone in View of Thomas et al., Buchholz et al. and Kampinga et al., further in View of Kuznicki et al.

At page 9, section 5 of the instant Office Action, claim 72 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al. and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619. The Office Action states that the cited references in combination make clear that the use of caffeine in rehydration solution is old and well known, and that the combination of references makes clear that the formulation containing diemthylglycine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known. The Office Action further states that it would have been apparent to those skilled in

the art to optimize amounts of known active and inactive ingredients in a composition. The Office Action is silent as to why Kampinga et al., in combination with the other cited references, would render the claimed invention obvious. Applicants respectfully traverse this rejection.

Claim 72 is directed to a fluid for treating hypohydration, comprising at least one methyl amine, one or more digestible carbohydrates and one or more minerals, wherein the methyl amine is selected from *dimethylglycine* and *sarcosine* with the amount of methyl amine being between 0.2 – 10 g/l, the digestible carbohydrate is in the amount of between 20 – 75 g/l, the mineral includes at least one of calcium and magnesium, and the fluid has an essentially hypotonic osmolality in the range of 70 to 275 mOsm/l, and wherein the fluid comprises glycerol, lipoic acid, a vitamin, citrate, phosphate, malate, taurine, caffeine or a combination thereof, and wherein caffeine is present in a concentration of 0.1-1 g/l.

Applicants have unexpectedly discovered that compositions for treating hypohydration containing dimethylglycine or sarcosine increase the viability of mammalian cells under dehydrating conditions in a clinical setting (*See* Attachment A). Applicants have experimentally determined that, in the presence of dimethylglycine or sarcosine, detrimental effects on cell viability due to dehydration could be avoided. Cells incubated in the presence of dimethylglycine or sarcosine under dehydrating conditions demonstrated a much improved growth rate over cells grown under the same dehydrating conditions in the absence of dimethylglycine or sarcosine. Applicants have further discovered that other organic osmolytes such as taurine, proline, myoinositol and urea did not show this beneficial effect and that organic osmolytes such as glycine, alanine and serine only demonstrated a minor beneficial effect. The rehydration art is silent as to *any* cell viability benefits provided by dimethylglycine or sarcosine under dehydrating conditions and fails to teach or suggest the desirability of adding either of these methyl amines to their compositions.

Applicants respectfully submit that the combination of cited references fails to render claim 72 obvious. The teachings of Simone, Thomas et al. and Buchholz et al. are described above.

Kampinga et al. is directed to a sports beverage containing the readily metabolizable, natural carbohydrate trehalose, that provides twice the concentration of glucose molecules for immediate energy compared to monosaccharide solutions of the same osmolarity (abstract). Kampinga et al. fails to teach or suggest a rehydration composition including sarcosine or dimethylglycine.

Kuznicki et al. teaches a rehydration composition that combines green tea solids, electrolytes and carbohydrates (abstract). Kuznicki et al. fails to teach or suggest a rehydration composition including sarcosine or dimethylglycine.

None of the **hydration** references cited by the Examiner teach the use of sarcosine or dimethylglycine in their formulations, or that these methyl amines may provide any benefits for treating hypohydration. The Office Action states that all the claimed ingredients were known to be useful in preparing **rehydration** drinks or solutions (page 8). Applicants disagree. The only reference cited by the Office Action that uses sarcosine or dimethylglycine, is Buchholz et al., and this reference is not directed to treating hypohydration, but to treating and preventing **transmethylation disorders**. Further, although Buchholz et al. teaches the use of sarcosine and dimethylglycine, it is because they are **methyl donors** that may be involved in **transmethylation**, i.e., transmethylation (column 3, lines 1-8; column 4, lines 62-65). Nowhere does Buchholz et al. teach that sarcosine or dimethylglycine may aid in the treatment of hypohydration, and one of skill in the art would have absolutely no reason to believe, based on the teachings of Buchholz et al., that this would be so. Buchholz et al. simply provides no motivation, teaching or suggestion to modify the teachings of Simone to arrive at the claimed invention.

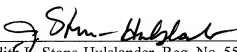
Accordingly, the combination of Simone in view of Thomas et al., Buchholz et al. and Kampinga et al., further in view of Kuznicki et al. fails to render claim 72 obvious. Thus, Applicants respectfully request that this rejection be reconsidered and withdrawn.

VI. Conclusion

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600. The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

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